DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M2545n

PURGED RK

April 22, 1999

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 26

Jim Ward
MN DAK Dairy
RR #1, Box 142A
Cleveland, Minnesota 56017

Dear Mr. Ward:

An investigation at your dairy operation located at Cleveland, Minnesota, conducted by our investigator on April 6, 1999, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmic Act (the Act).

On or about February 10, 1999, you sold a dairy cow, identified with ear tag 1516, for slaughter as human food, to [redacted] U.S. Department of Agriculture (USDA) analysis of tissue samples collected from the animal identified the presence of 17.00 parts per million (ppm) oxytetracycline in the kidney. A tolerance of 12 ppm has been established for residues of oxytetracycline in the fat and kidney of lactating dairy cows. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack

records to positively identify treated animals, to identify the drug or drugs used to treat the animals, or to identify the route of administration, dosage, time of treatment, duration of treatment, and withdrawal time. Foods from animals held under such conditions are adulterated.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,

James A. Rahto
Director
Minneapolis District